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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/966,939	09/28/2001	Harry S. Sowden	MCP-0242	5012
27777	7590	02/09/2004	EXAMINER	
PHILIP S. JOHNSON JOHNSON & JOHNSON ONE JOHNSON & JOHNSON PLAZA NEW BRUNSWICK, NJ 08933-7003			DAVIS, ROBERT B	
		ART UNIT	PAPER NUMBER	
		1722	24	

DATE MAILED: 02/09/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	09/966,939	SOWDEN ET AL.
	Examiner Robert B. Davis	Art Unit 1722

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 08 October 2003.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 34-45 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 34,35 and 37-45 is/are rejected.
- 7) Claim(s) 36 is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>22, 23</u> . | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Objections

1. Claims 37-39 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claims 37-39 merely further define the material being worked upon (flowable material) and do not further limit the structure of the apparatus. These claims should be canceled or amended to further define the structure of the apparatus.
2. The indicated allowability of claims 34, 35 and 37-45 is withdrawn in view of the newly discovered reference(s) to Sawada et al and Bar-Shalom. Rejections based on the newly cited reference(s) follow.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 34, 35, 37-39 and 41-44 are rejected under 35 U.S.C. 103(a) as being unpatentable over UK specification (759,081: page 1, lines 13-15 and 27-45; page 2, lines 37-45 and page 3, lines 32-45 and 57-65) taken together with Sawada et al (US2002/0028240 A1: paragraph 87).

Art Unit: 1722

The UK specification discloses an apparatus for making a coated dosage form comprising: a compression module (2) having means for forming compressed dosage forms by compressing a powder (opposed tablet presses 7, 8), a transfer device (27) having means (33, 34) for continuously transferring a compressed form (46) from the compression module to a second compression module, and a second compression module (12) for compression coating the previously shaped module to form a coated dosage form with opposed tablet presses (14, 17). The reference teaches a second compression module instead of a thermal cycle molding module. The reference teaches a transfer spindle (29) that is simultaneously rotated by a suitable driving mechanism simultaneously with the tables (2 and 12). The first table (2) has a plurality of dies (3) and the coating table (12) has a plurality of coating dies (19). It is inherent that a motor is a suitable driving mechanism.

Sawada et al disclose a device for manufacturing a coated dosage form by coating a preformed core by either compression coating or by an injection molding module wherein the coating is melted to coat the previously formed core.

It would have been obvious at the time of the invention to one of ordinary skill in the art to modify the apparatus of the UK specification by substituting an injection molding die for the compression coating die as Sawada et al disclose that injection molding dies and compression molding dies are well known alternative coating dies used to form dosage forms. One of ordinary skill in the art would expect an injection molding die to function properly to form a coated dosage form based on the alternative teaching of Sawada et al.

Art Unit: 1722

5. Claim 45 is rejected under 35 U.S.C. 103(a) as being unpatentable over the UK specification taken together with Sawada et al as applied to claims 34, 35, 37-39 and 41-44 above, and further in view of Rosato et al (Mold Making Handbook, page 189, second column, figure 29-35 on page 794 and numbered paragraph 4 on page 795).

The combination of the UK specification and Sawada et al disclose all claimed features except for the injection mold comprising a heat source, a heat sink, a temperature control system, a tubing system disposed proximal to the mold cavities and running through the heat sink and heat source.

Rosato et al disclose that heating and cooling systems in an injection mold are formed by fluid passages wherein the mold cavities are heated and cooled (page 189). Figure 29-35 shows side-by-side heating and cooling channels proximal to the mold cavity for heating and cooling the cavity. It is inherent that a heat sink and a heat source would be attached to the cooling and heating circuits associated with the heating and cooling channels for the purpose of returning a heat exchange fluid to a desired temperature for heating and cooling a mold cavity as controlled by a controller.

It would have been obvious at the time of the invention to modify the apparatus of the combination of the UK specification and Sawada et al by providing heating and cooling channels proximal to the mold cavity for the purpose of providing an improved surface to the molded article (heating p. 795 Rosato et al) and short cycle times (cooling p. 795 Rosato et al.)

6. Claim 40 is rejected under 35 U.S.C. 103(a) as being unpatentable over the UK specification taken together with Sawada et al as applied to claims 34, 35, 37-39 and

Art Unit: 1722

41-44 above, and further in view of Bar-Shalom (5,213,808: figures 11a-11e; column 19, lines 24-45 and column 21, lines 24-68).

The combination of the UK specification and Sawada et al disclose all claimed features except for the use of an injection mold for coating different materials onto different portions an insert to form a coated dosage form.

Bar-Shalom discloses an injection mold as shown in figures 11a-11e which forms a first injection molded coating (2,2) over an insert (1) as shown in figure 11b, and a second injection molding coating (5,5) as shown in figure 11c for the purpose of controlling the release properties of the dosage form by coating the insert (1) with materials that erode at different rates.

It would have been obvious at the time of the invention to one of ordinary skill in the art to modify the apparatus of the combination of the UK specification and Sawada et al by using a two-step injection mold which allows for coating of an insert with different materials to control the release properties of the dosage form inside an animal body.

Allowable Subject Matter

7. Claim 36 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

8. The following is a statement of reasons for the indication of allowable subject matter: None of the prior art of record teach or suggest an apparatus for forming a coated dosage form comprising a thermal setting module for forming an insert

Art Unit: 1722

containing a second medicant, means for embedding the insert into a dosage form prior to molding the coating in the apparatus of claim 34. Sawada et al suggest an apparatus having a compression molded core and an injection mold for forming a coating, but fails to disclose or suggest injection molding a thermal setting insert, and a compression mold for embedding the insert in the compressed dosage form and then injection molding a coating over the dosage form. Bar-Shalom disclose injection molding an insert and then injection molding a coating but fail to disclose or suggest the inject mold, compression mold and finally a second injection mold combination as claimed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert B. Davis whose telephone number is 571-272-1129. The examiner can normally be reached on Monday-Friday 9-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Wanda L. Walker can be reached on 571-272-1151. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should

Art Unit: 1722

you have questions on access to the Private PAIR system, contact the Electronic
Business Center (EBC) at 866-217-9197 (toll-free).



Robert B. Davis
Primary Examiner
Art Unit 1722

2/5/04